

16. 510(k) SUMMARY

APR 25 1997

Nature's Cradle® C2000 Series, when used as directed, is an infant motion and sound system designed to closely simulate the mother's heartbeat and circulatory system familiar to the infant during the last trimester of pregnancy. This provides a transition to infants after birth, allowing them to grow accustomed to their new environment at a pace that minimizes stress. Nature's Cradle® C2000 Series can be used with Infant Advantage® approved bassinets and hospital nursery tubs or bassinets. Nature's Cradle® C2000 Series is indicated for healthy, full term infants at home or hospital.

Nature's Cradle® C2000 Series uses the same motion and the same sound as predicate devices, Nature's Cradle® Model C1500, Premarket Notification # K960747, and Nature's Cradle® Model M-1, Premarket Notification # 901763. Nature's Cradle® C2000 Series uses the same mechanism as predicate device, Nature's Cradle® Model C1500, Premarket Notification # K960747.

The size of the moving platform of Nature's Cradle® C2000 Series has been reduced to allow the plastic case (containing mechanism and moving platform) to fit Infant Advantage® approved bassinets and hospital nursery tubs/bassinets.

Contrary to predicate devices (Nature's Cradle® Model C1500, Premarket Notification # K960747), the mechanism is no longer embedded in a 4 1/2" high mattress, or cabinet with 2" high mattress (Nature's Cradle® Model M-1, Premarket Notification # K901763). The modification of Nature's Cradle® C2000 Series makes the mechanism a stand alone device weighing approximately 5 pounds that is covered with a 1" high mattress.

Contrary to predicate devices, Nature's Cradle® Model C1500, Premarket Notification # K960747 and Nature's Cradle® Model M-1, Premarket Notification # K901763 which are intended to be used at home only, the new Nature's Cradle® C2000 Series can be used for healthy, full term infants at home or hospital from 0 - 16 weeks. The fundamentals of the principles remain the same as with predicate devices, Nature's Cradle® Model C1500, Premarket Notification # K960747, and Nature's Cradle® Model M-1, Premarket Notification # K901763.

The mechanism of Nature's Cradle® C2000 Series is connected to the same control module and the same low voltage wall-mount transformer as predicate device, Nature's Cradle® Model C1500, Premarket Notification # K960747.

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A mattress is provided separately and placed on top of the platform, the same as predicate device, Nature's Cradle® Model M-1, Premarket Notification # K901763. To further enhance the safety of the device, the fitted sheet is placed over the top of the bassinet or tub and secured with a cord. To further enhance the safety of the device, the fitted sheet is placed over the top of the bassinet or tub and secured with a cord. This feature keeps the infant in a "Hammock"-like surrounding, on the mattress, and away from the walls of the bassinet or tub. Furthermore, the Nature's Cradle® C2000 Series includes the same safety checks in the mechanism as predicate devices, Nature's Cradle® Model C1500, Premarket Notification # K960747, and Nature's Cradle® Model M-1, Premarket Notification # K901763: any excessive weight or obstruction of the moving platform will immediately stop the mechanism.

All components of Nature's Cradle® C2000 Series are non-sterile and reusable.

The Nature's Cradle® C2000 Series has the same device classification product code (80FMS), the same technology and fundamentals of principles, and the same indications for use as legally marketed, predicate devices, Nature's Cradle® Model C1500, Premarket Notification # K960747, and Nature's Cradle® Model M-1, Premarket Notification # K901763.

Laboratory and bench testing of predicate device, Nature's Cradle® Model C1500, Premarket Notification # K960747 demonstrated the device to be safe and effective when used as described. The new Nature's Cradle® C2000 Series has not been modified significantly and has the same fundamentals of principles as predicate device, Nature's Cradle® Model C1500, Premarket Notification # K960747, except for a smaller size platform. This change does not require additional testing and reliability data was submitted with predicate device, Nature's Cradle® Model C1500, Premarket Notification # K960747 and is included in Section 18, Attachment IV.

A clinical trial, published in the Journal of Perinatology Vol. 15, No. 3, 1995, involving 90 full term infants was performed at Kaiser Medical Center, Santa Clara, CA. The infants were evaluated utilizing the Brazelton Neonatal Behavior Assessment Scale. The study found that infants who sleep in the Nature's Cradle® environment were more adaptive, less irritable, and cried approximately 65% less. Additionally, they were more attentive, and alert, slept for longer periods, and slept through the night sooner, plus experienced a lower incidence of colic when compared to the control group.

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Clinical data submitted for predicate device, Nature's Cradle® Model M-1, Premarket Notification # K901763 demonstrated that the device is safe and effective for use with healthy, full-term infants at home. The same data was used for Nature's Cradle® Model C1500, Premarket Notification # K960747. Clinical data are enclosed in Section 19, Attachments I - VI.

The device is available without a prescription, the same as predicate devices, Nature's Cradle® Model C1500, Premarket Notification # K960747, and Nature's Cradle® Model M-1, Premarket Notification # K901763.

Adequate warnings and cautions for safe and effective use of the product have been incorporated in the product labeling.

Substantial equivalence to legally marketed predicate devices with the same indications for use has been demonstrated by comparison of product features as described in Premarket Notification # K960747 for Nature's Cradle® Model C1500, and Premarket Notification # K901763 for Nature's Cradle® Model M-1, product labeling and promotional materials. Copies of the labeling of predicate device, Nature's Cradle® Model C1500, Premarket Notification # K960747 is included in Section 18, Attachment IX, and labeling of predicate device, Nature's Cradle® Model M-1, Premarket Notification # K901763, is included in Section 18, Attachment X.